DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2015

Roosin Medical Co., Ltd.
% Mr. Charles Shen
Manton Business and Technology Services
853 Dorchester Lane, Unit-B
New Milford, New Jersey 07646

Re: K143335
Trade/Device Name: Roosin Silver Calcium Alginate Dressing (Prescription);
Roosin Alginate Dressing with Preservative (OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 1, 2015
Received: June 1, 2015

Dear Mr. Shen:

This letter corrects our substantially equivalent letter of June 1, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143335

Device Name
Roosin Silver Calcium Alginate Dressing (Prescription)
Roosin Alginate Dressing with Preservative (OTC)

Indications for Use *(Describe)*

Prescription:
Roosin Silver Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites

OTC:
First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Roosin Medical Co., Ltd.
8 Yuandong Road, KouAn Town, Gaogang,
Taizhou, Jiangsu Province, China 225321
Tel: (086) 523-86908085
Submitter's FDA Registration Number: 3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester LN, Unit-B
New Milford, NJ 07646
Tel: 608-217-9358
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Date of Summary: June 1, 2015

Device Name:

Trade Name:	Roosin Silver Calcium Alginate Dressing (Prescription) Roosin Alginate Dressing with Preservative (OTC)
Common Name:	Silver Alginate Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K120181: "Luofucon Silver Alginate Dressing (Prescription Use)/ Luofucon Antibacterial Alginate Dressing (OTC Use)", manufactured by "Huizhou Foryou Medical devices Co., Ltd." located in Huizhou, Guangdong Province, China

Device description:

Roosin Silver Calcium Alginate Dressing/ Roosin Alginate Dressing with Preservative is a sterile, non-woven pad composed of a high G (guluronic acid) calcium alginate and silver particles, which absorbs wound exudate and releases silver in the presence of

wound fluid. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The alginate material consists of silver that controls bacterial growth within the dressing. Based on in vitro laboratory testing, the silver has been shown to protect the dressing against both Gram positive and Gram negative bacteria, such as *Escherichia coli, Klebsiella pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis,* and *Streptococcus pyogenes.* The in vitro test was for one day only, so the user is advised to change the dressing every day for antibacterial preservative use.

The dressing has an off-white appearance and is available in the form of pad and in three different sizes (50 mm x 50 mm, 60 x 70 mm, 100 mm x 100 mm, 100 mm x 150 mm, and 20 mm x 300 mm), packaged in pouches. Additional sizes may also be manufactured per customer request. All dressings have the exactly the same material, chemical, and physical properties and are different only in size.

All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Product Information:

Preservative Agent:	Silver Particles
Target Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	In vitro test results show antibacterial preservative effect for for 24 hours against Gram positive and Gram negative bacteria such as *Escherichia coli, Klebsiella pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis,* and *Streptococcus pyogenes.*
Concentration on the device:	Each 100 mm x 100 mm dressing contains 16.0 mg (1.4% w/w) silver particles

Intended Use:

Prescription:
Roosin Silver Calcium Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites

OTC:
First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

Comparison to Predicate Devices

Roosin Silver Calcium Alginate Dressing/ Roosin Alginate Dressing with Preservative is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K120181: "Luofucon Silver Alginate Dressing (Prescription Use)/ Luofucon Antibacterial Alginate Dressing (OTC Use)", manufactured by "Huizhou Foryou Medical devices Co., Ltd." located in Huizhou, Guangdong Province, China

Both Roosin Silver Calcium Alginate Dressing/Roosin Alginate Dressing with Preservative and its predicate devices utilize silver to control bacterial growth within the dressing.

Both Roosin Silver Calcium Alginate Dressing/Roosin Alginate Dressing with Preservative and its predicate device utilize calcium alginate for the exudate absorption and wound management.

Roosin Silver Calcium Alginate Dressing/Roosin Alginate Dressing with Preservative and its predicate devices are made from similar materials, utilize the same mechanism to preserve the dressing, and have the same intended use.

Roosin Silver Calcium Alginate Dressing/Roosin Alginate Dressing with Preservative meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2012. The product is safe and effective for its intended use.

Antibacterial activity was measured following AATCC 100-2004 for total of six clinical relevant bacteria to evaluate antibacterial preservative effectiveness. Roosin Silver Calcium Alginate Dressing/Roosin Alginate Dressing with Preservative is effective (>99.99% reduction) for all 6 bacteria and effect lasts for one day.

The results are comparable to the predicate devices when the dressings are used for preservative purpose and changed at 24-hour time intervals. Clinical data is not provided for this device.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Roosin Silver Calcium Alginate Dressing/Roosin Alginate Dressing with Preservative is substantial equivalent to its predicate devices.